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(54) **CATHETER GUIDANCE THROUGH A
CALCIFIED AORTIC VALVE**

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(75) Inventor: **Randall T. Lashinski**, Santa Rosa, CA
(US)

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(73) Assignee: **Direct Flow Medical, Inc.**, Santa Rosa,
CA (US)

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

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(22) Filed: **Oct. 18, 2007**

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19, 2006.

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A61M 31/00 (2006.01)

(52) **U.S. Cl.** **604/509**; 604/510; 604/104; 606/194

(58) **Field of Classification Search** 604/507-510,
604/96.01, 104-107, 108, 109; 606/191,
606/192, 194, 198; 623/1.11, 1.12, 2.11;
128/898

See application file for complete search history.

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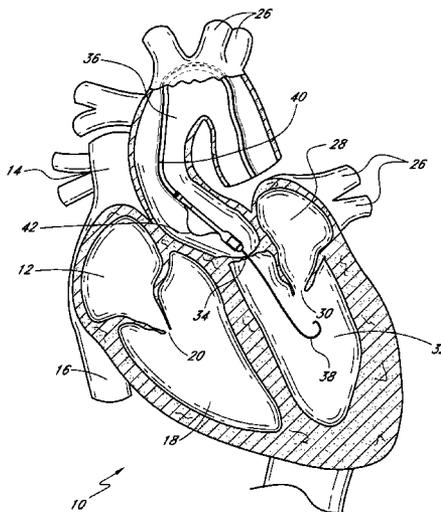
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(57) **ABSTRACT**

A method of treating a patient with a calcified aortic valve
includes introducing a guide wire into a blood vessel. The
guide wire is advanced through the aorta and the aortic valve.
A balloon dilatation catheter is introduced into the blood
vessel over the guide wire. The balloon dilatation catheter
includes an elongate body, a distal portion, a guide wire
lumen, an inflation lumen, and a dilatation balloon. The bal-
loon dilatation catheter further includes at least one deflection
wire lumen, and at least one deflection wire residing in the at
least one deflection wire lumen and having a distal end
attached to the distal portion. The balloon dilatation catheter
is advanced over the guide wire through the aorta. The deflec-
tion wire is pushed towards the distal portion so that the
deflection wire bows outward. The balloon dilatation catheter
is advanced through the aortic valve, and the dilatation bal-
loon is inflated.

5 Claims, 10 Drawing Sheets



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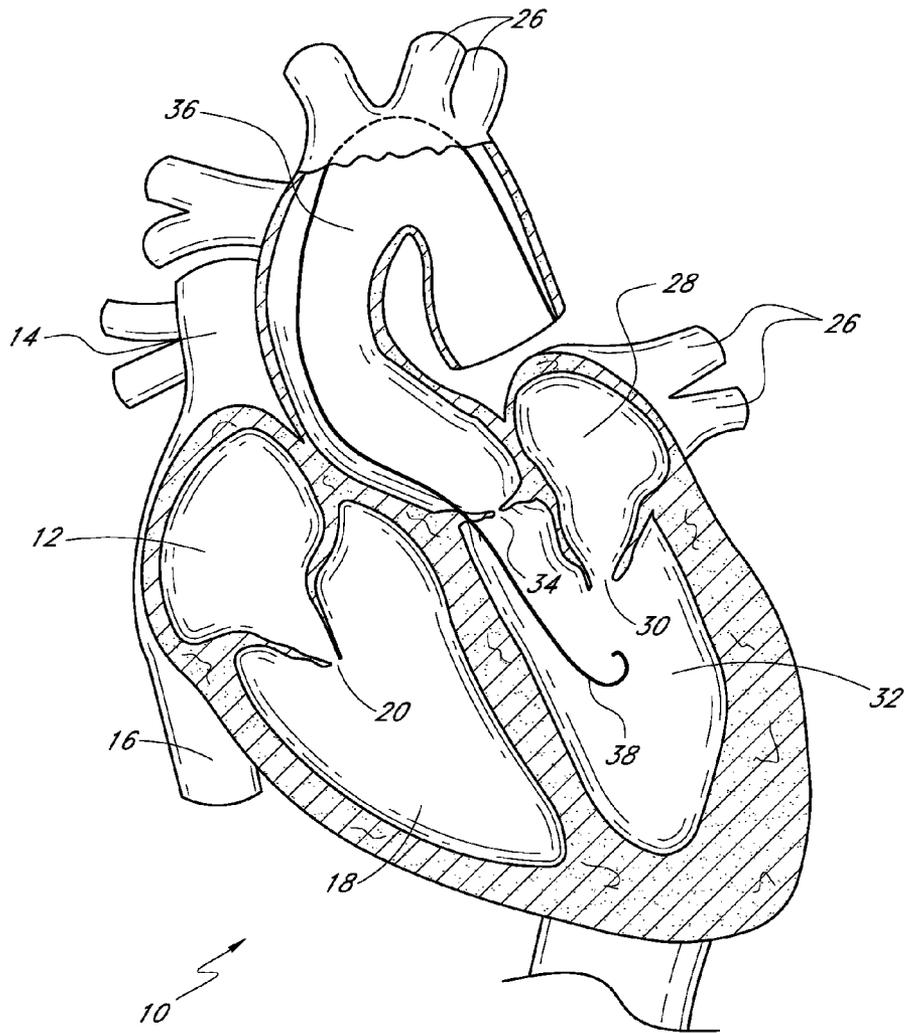
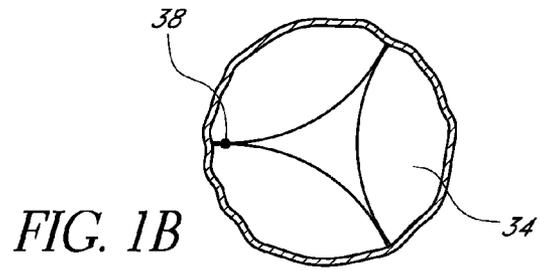
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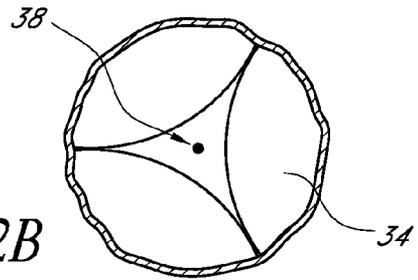


FIG. 2B

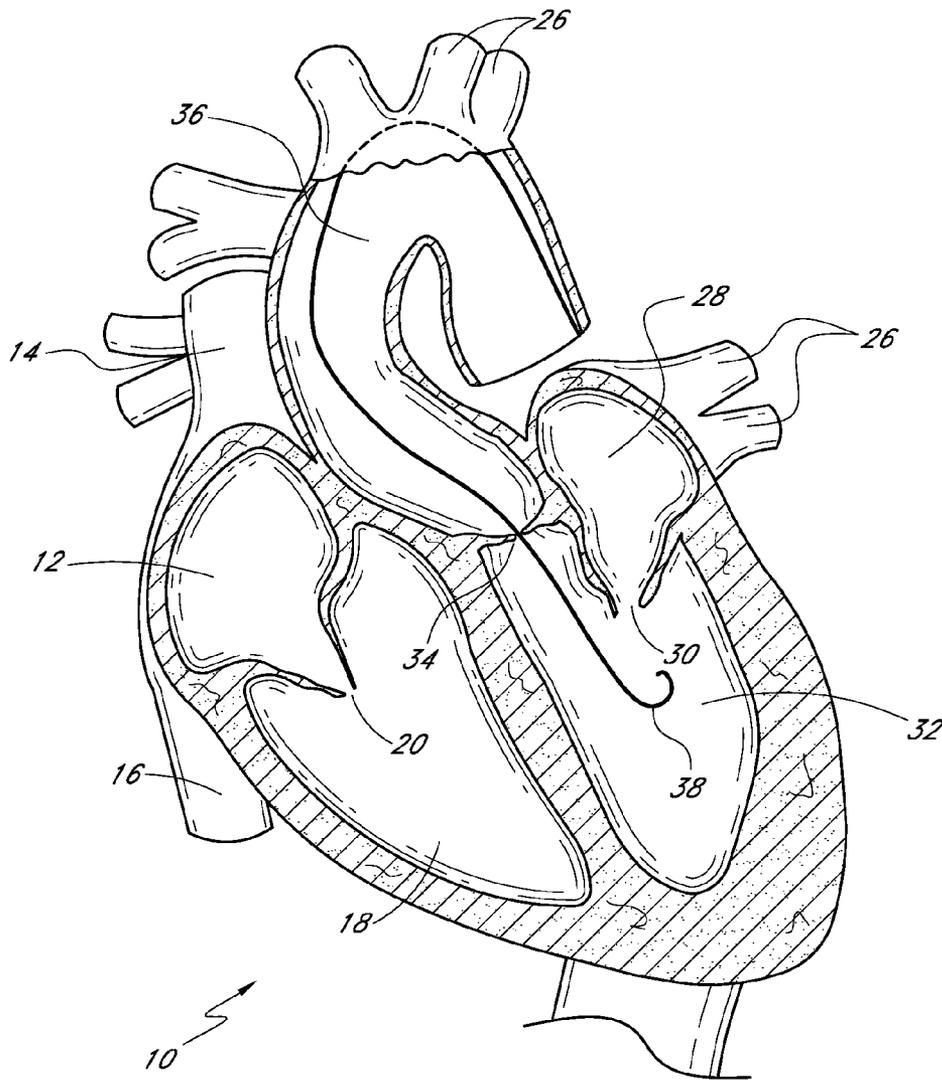


FIG. 2A

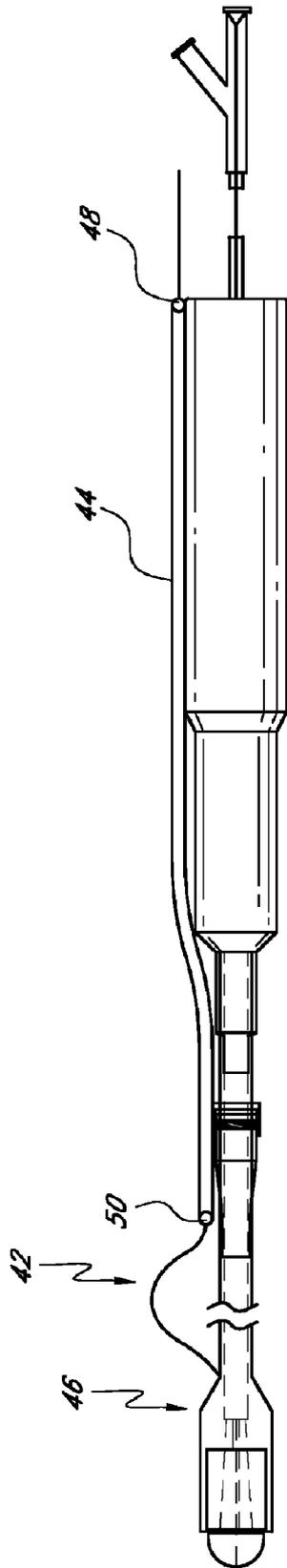


FIG. 3A

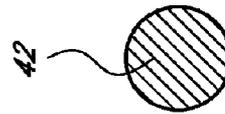
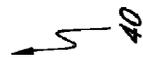


FIG. 3C

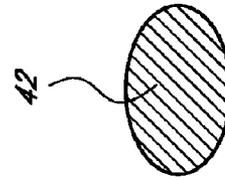


FIG. 3D

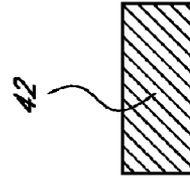


FIG. 3E

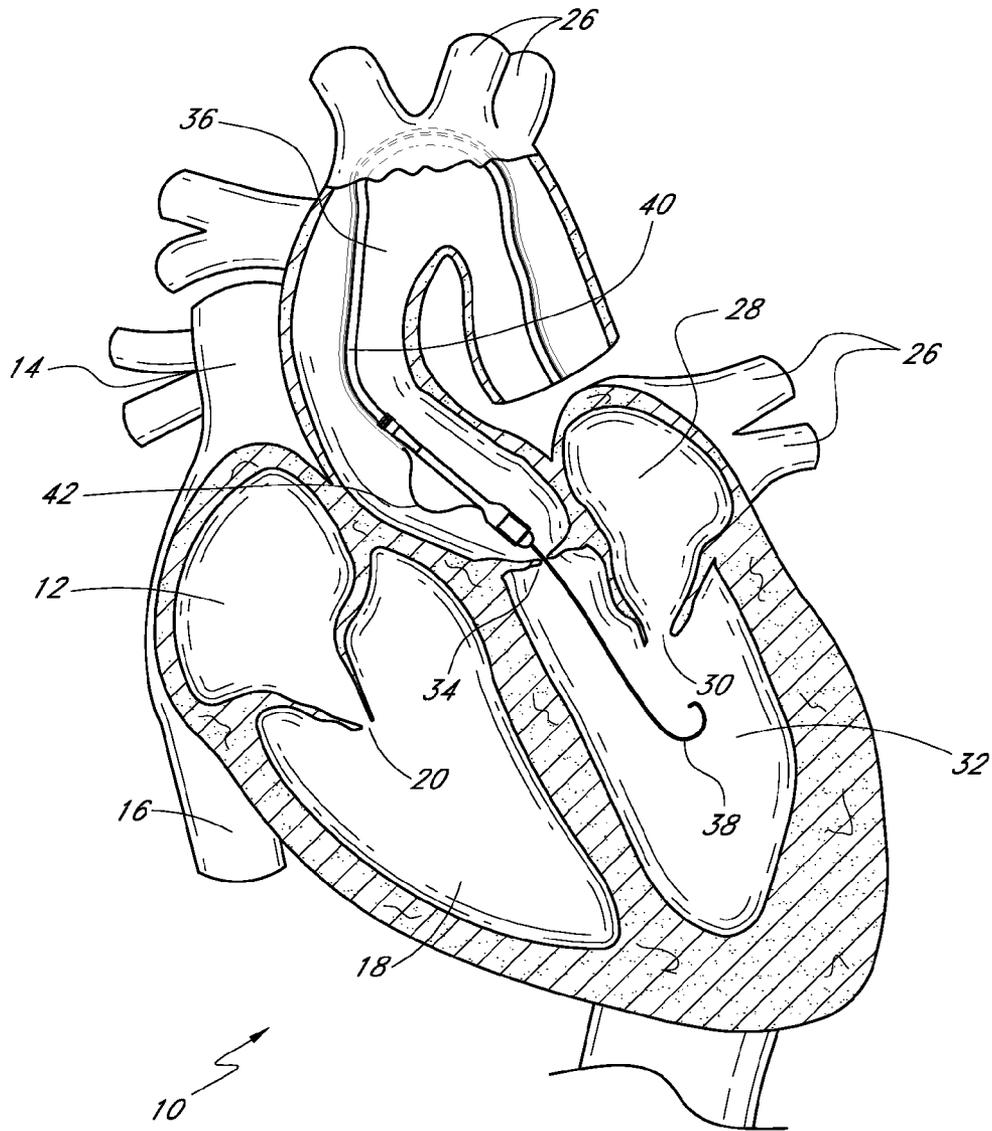


FIG. 3B

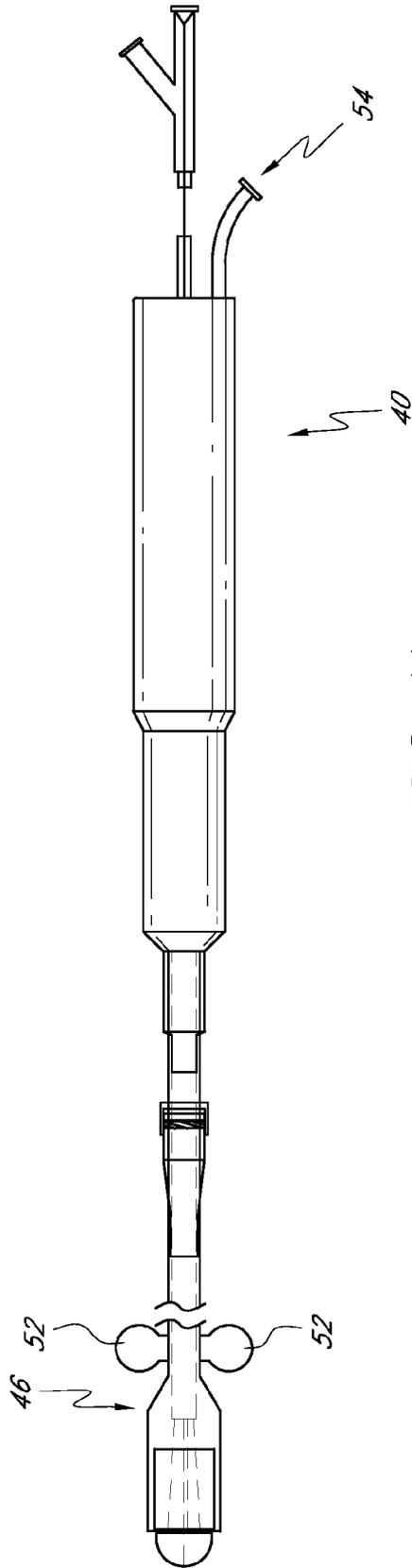


FIG. 4A

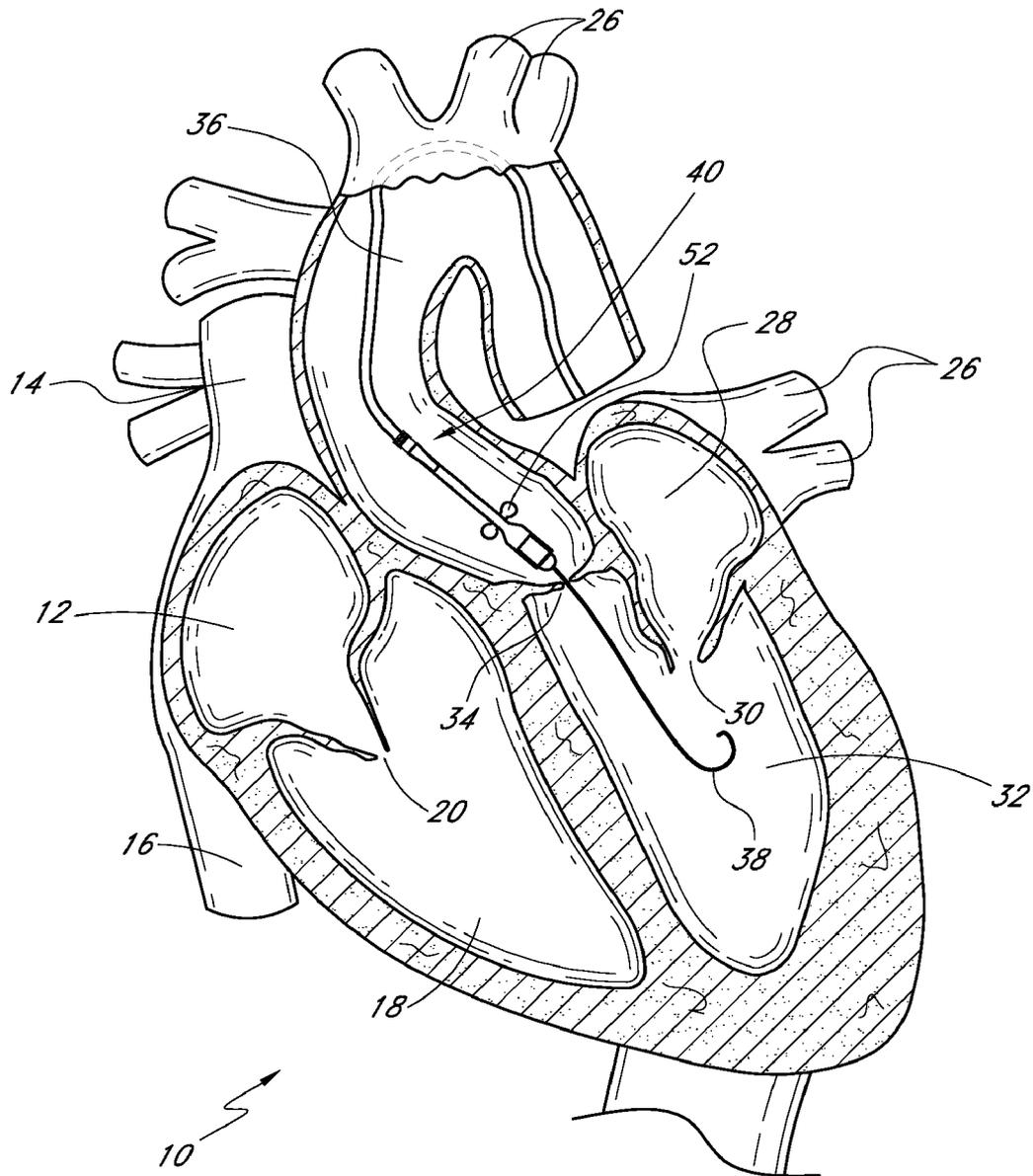


FIG. 4B

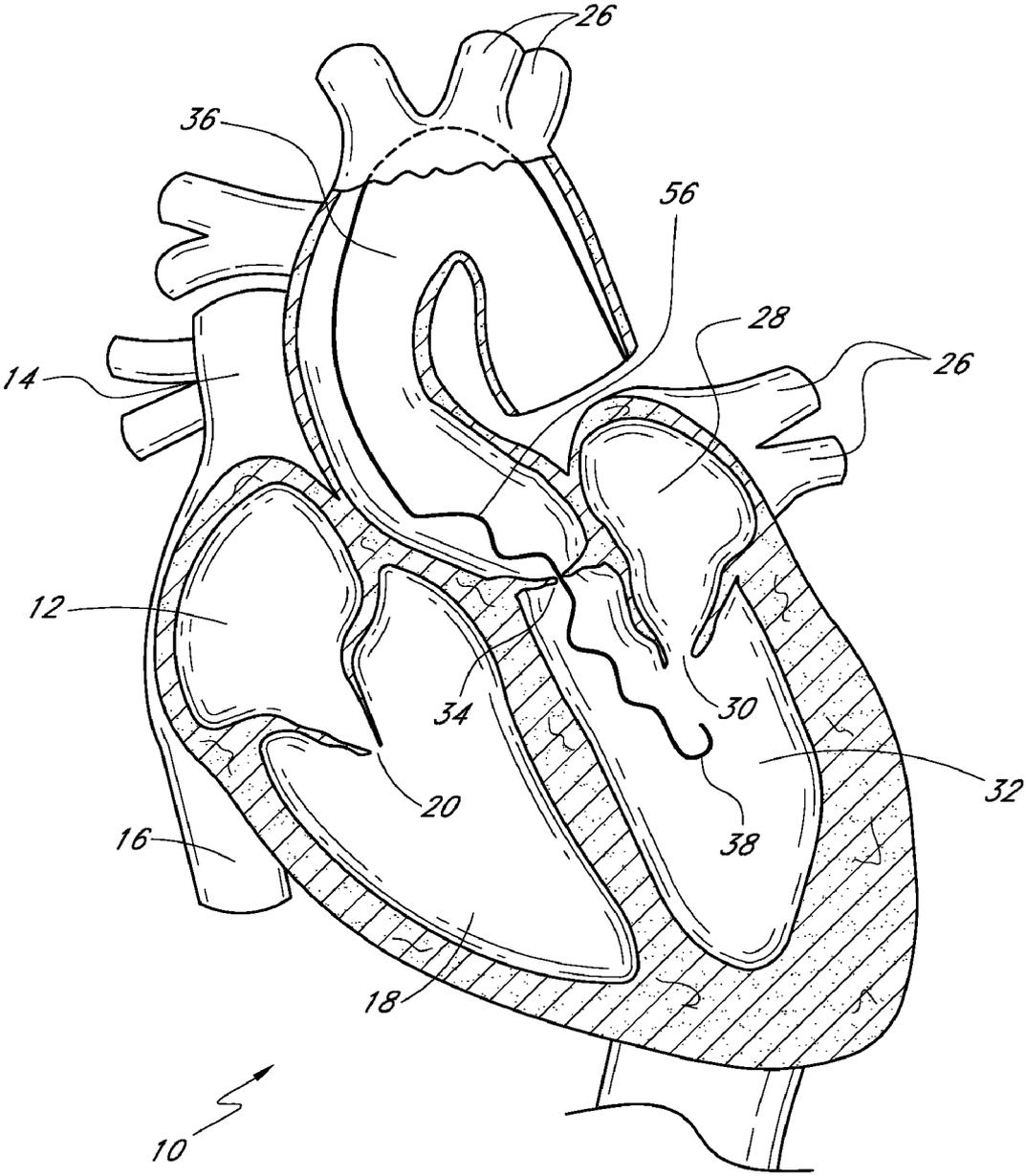


FIG. 5

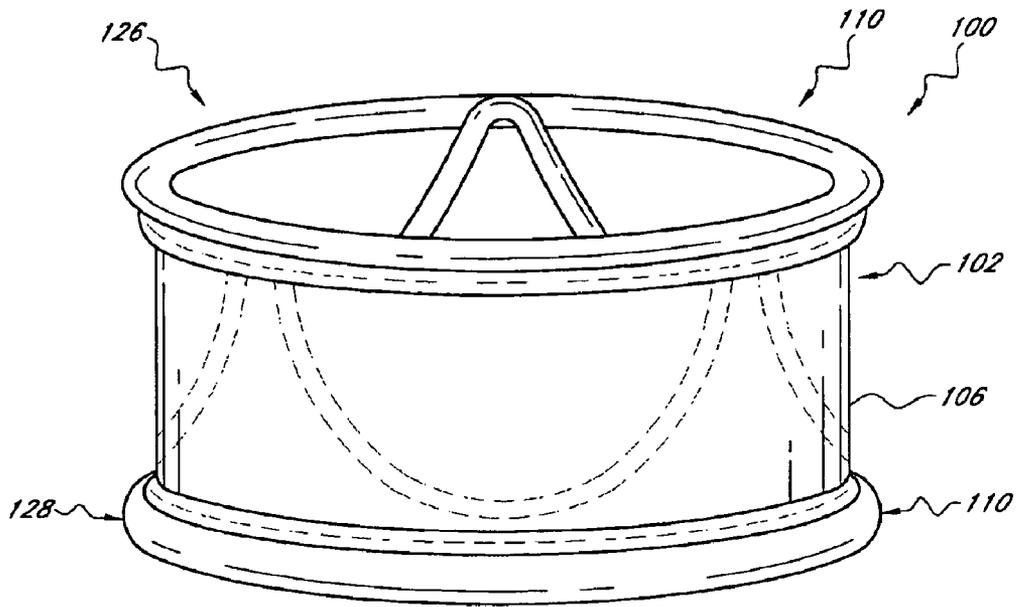


FIG. 6A

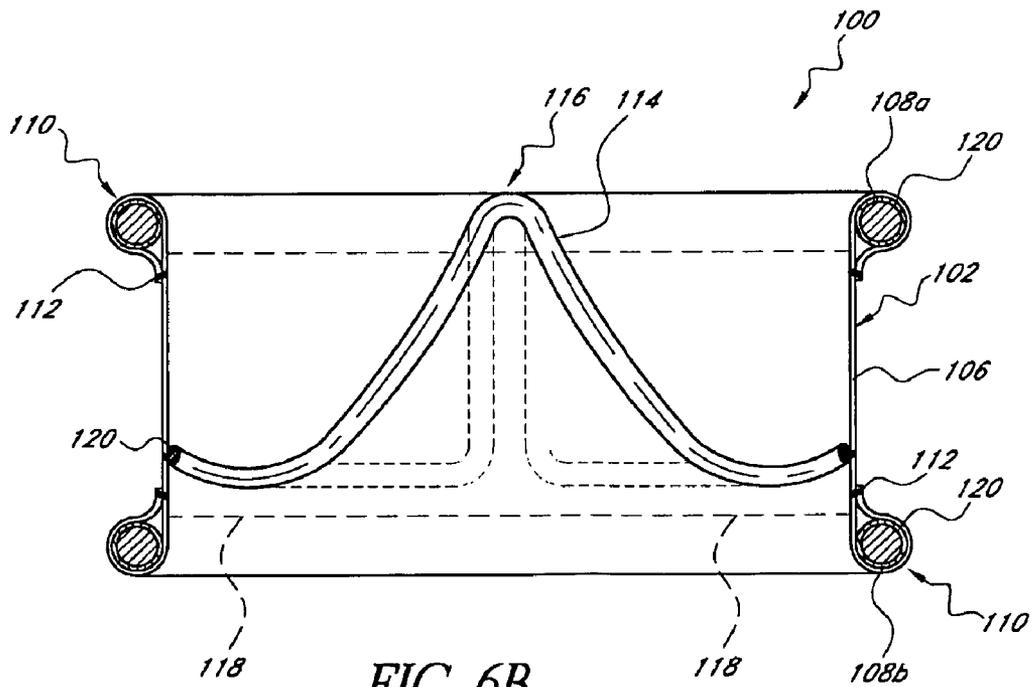


FIG. 6B

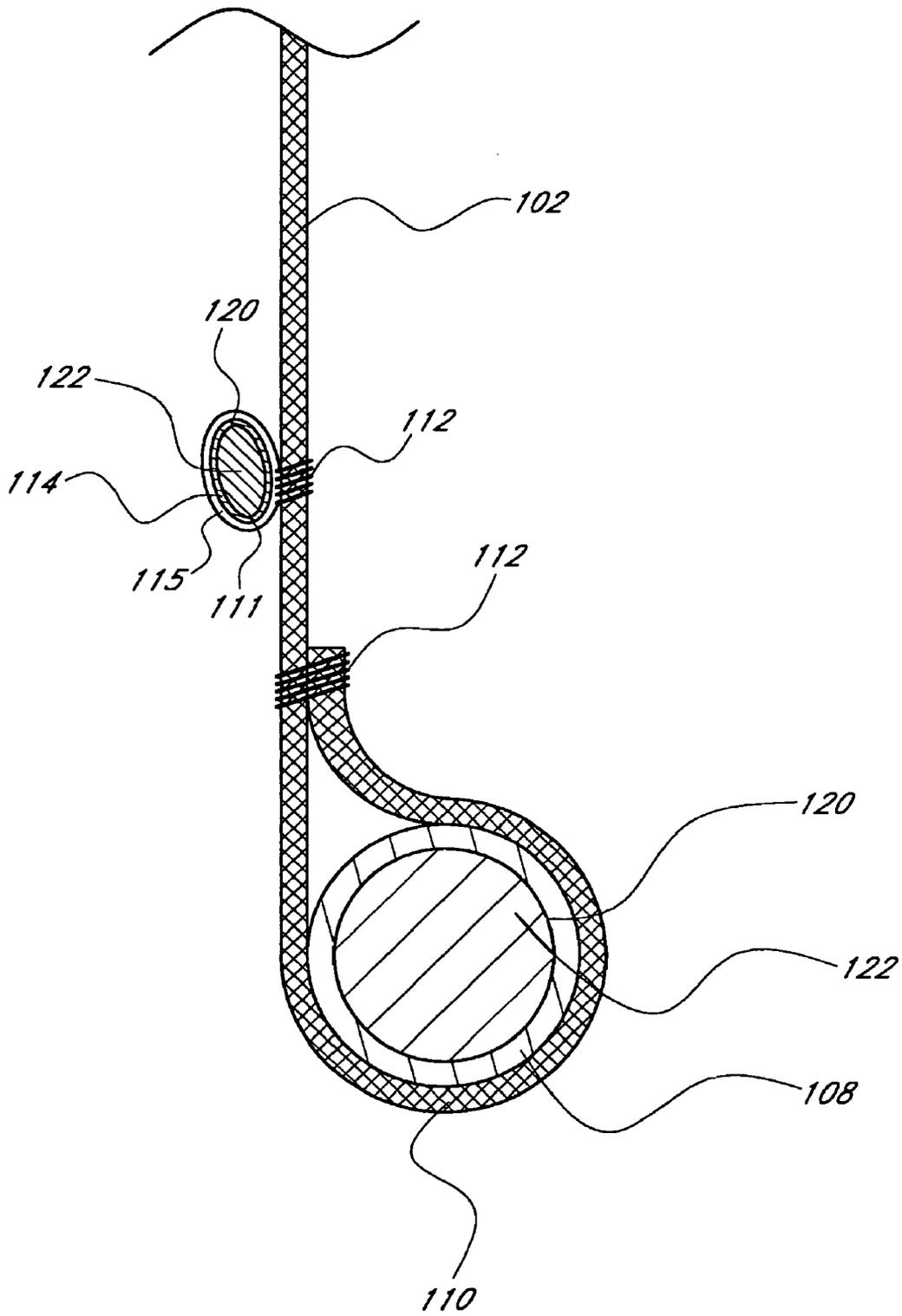


FIG. 6C

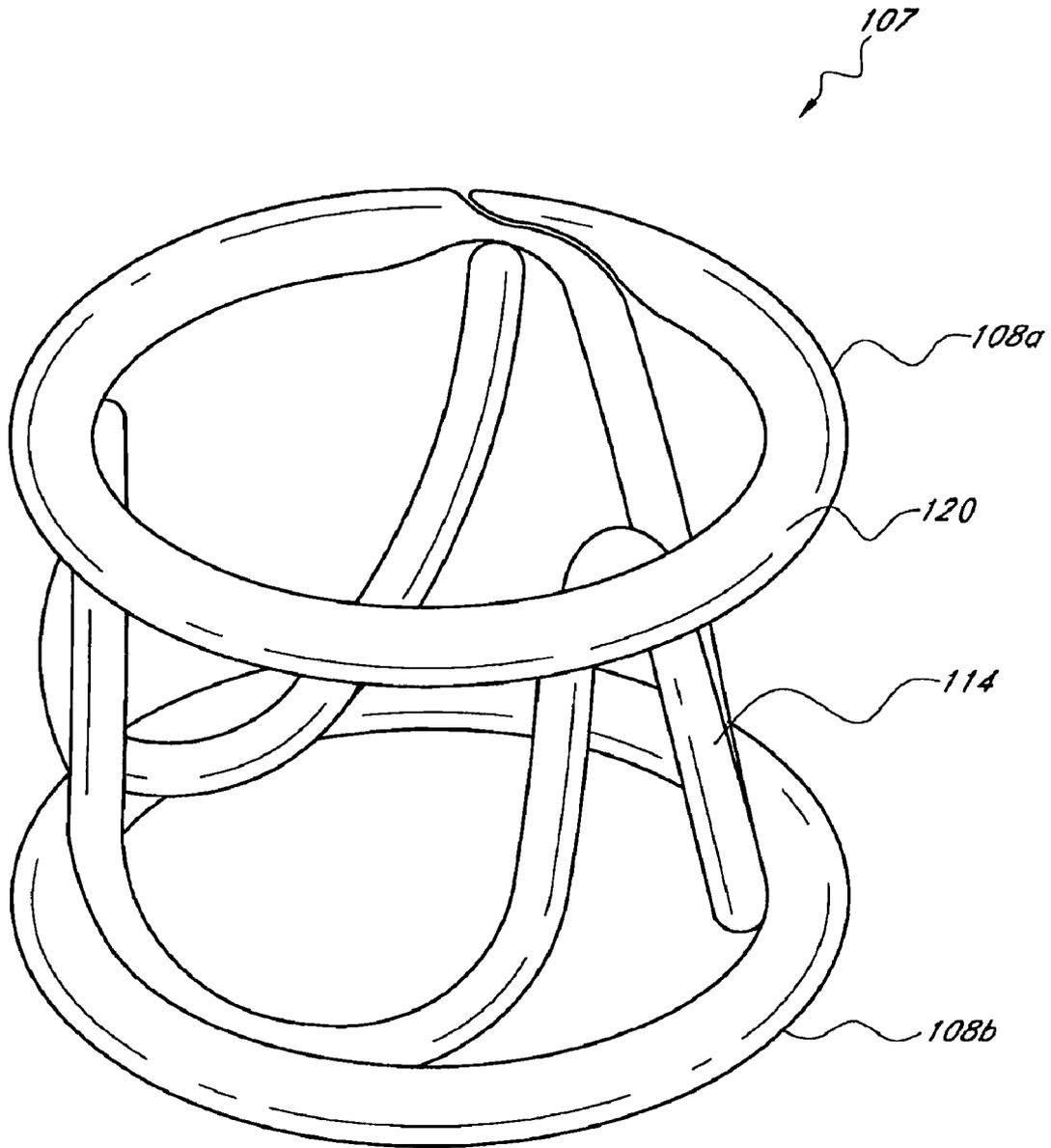


FIG. 6D

CATHETER GUIDANCE THROUGH A CALCIFIED AORTIC VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the priority benefit to U.S. Provisional No. 60/862,187 filed Oct. 19, 2006, the entirety of which is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to medical methods and devices, and, in particular, to methods and devices for guiding a catheter through an aortic valve.

2. Description of the Related Art

According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

The circulatory system is a closed loop bed of arterial and venous vessels supplying oxygen and nutrients to the body extremities through capillary beds. The driver of the system is the heart providing correct pressures to the circulatory system and regulating flow volumes as the body demands. Deoxygenated blood enters heart first through the right atrium and is allowed to the right ventricle through the tricuspid valve. Once in the right ventricle, the heart delivers this blood through the pulmonary valve and to the lungs for a gaseous exchange of oxygen. The circulatory pressures carry this blood back to the heart via the pulmonary veins and into the left atrium. Filling of the left atrium occurs as the mitral valve opens allowing blood to be drawn into the left ventricle for expulsion through the aortic valve and on to the body extremities. When the heart fails to continuously produce normal flow and pressures, a disease commonly referred to as heart failure occurs.

Heart failure simply defined is the inability for the heart to produce output sufficient to demand. Mechanical complications of heart failure include free-wall rupture, septal-rupture, papillary rupture or dysfunction aortic insufficiency and tamponade. Mitral, aortic or pulmonary valve disorders lead to a host of other conditions and complications exacerbating heart failure further. Other disorders include coronary disease, hypertension, and a diverse group of muscle diseases referred to as cardiomyopathies. Because of this syndrome establishes a number of cycles, heart failure begets more heart failure.

Heart failure as defined by the New York Heart Association in a functional classification.

I. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.

II. Patient with cardiac disease resulting in slight limitation of physical activity. These patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.

III. Patients with cardiac disease resulting in marked limitation of physical activity. These patients are comfortable at rest. Less than ordinary physical activity causes fatigue palpitation, dyspnea, or anginal pain.

IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms

of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

There are many styles of mechanical valves that utilize both polymer and metallic materials. These include single leaflet, double leaflet, ball and cage style, slit-type and emulated polymer tricuspid valves. Though many forms of valves exist, the function of the valve is to control flow through a conduit or chamber. Each style will be best suited to the application or location in the body it was designed for.

Bioprosthetic heart valves comprise valve leaflets formed of flexible biological material. Bioprosthetic valves or components from human donors are referred to as homografts and xenografts are from non-human animal donors. These valves as a group are known as tissue valves. This tissue may include donor valve leaflets or other biological materials such as bovine pericardium. The leaflets are sewn into place and to each other to create a new valve structure. This structure may be attached to a second structure such as a stent or cage or other prosthesis for implantation to the body conduit.

Implantation of valves into the body has been accomplished by a surgical procedure and has been attempted via percutaneous method such as a catheterization or delivery mechanism utilizing the vasculature pathways. Surgical implantation of valves to replace or repair existing valves structures include the four major heart valves (tricuspid, pulmonary, mitral, aortic) and some venous valves in the lower extremities for the treatment of chronic venous insufficiency. Implantation includes the sewing of a new valve to the existing tissue structure for securement. Access to these sites generally include a thoracotomy or a sternotomy for the patient and include a great deal of recovery time. An open-heart procedure can include placing the patient on heart bypass to continue blood flow to vital organs such as the brain during the surgery. The bypass pump will continue to oxygenate and pump blood to the body's extremities while the heart is stopped and the valve is replaced. The valve may replace in whole or repair defects in the patient's current native valve. The device may be implanted in a conduit or other structure proper or supporting tissue surrounding the heart. Attachments methods may include suturing, hooks or barbs, interference mechanical methods or an adhesion median between the implant and tissue.

Although valve repair and replacement can successfully treat many patients with valvular insufficiency, techniques currently in use are attended by significant morbidity and mortality. Most valve repair and replacement procedures require a thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing the two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents. Alternatively, a thoracotomy may be performed on a lateral side of the chest, wherein a large incision is made generally parallel to the ribs, and the ribs are spread apart and/or removed in the region of the incision to create a large enough opening to facilitate the surgery.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta to occlude the aortic lumen between the brachiocephalic artery and the coronary ostia.

Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the ascending aorta, to arrest cardiac function. The patient is placed on extracorporeal cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Since surgical techniques are highly invasive and in the instance of a heart valve, the patient must be put on bypass during the operation, the need for a less invasive method of heart valve replacement has long been recognized.

SUMMARY OF THE INVENTION

One embodiment of the present invention comprises a method of treating a patient with a calcified aortic valve. The method comprises introducing a guide wire into a blood vessel. The guide wire is advanced through the aorta to the aortic valve and then through the aortic valve. A balloon dilatation catheter is introduced into the blood vessel over the guide wire.

The balloon dilatation catheter comprises an elongate body, a distal portion, a guide wire lumen, an inflation lumen, and a dilatation balloon. The balloon dilatation catheter further comprising at least one deflection wire lumen, the at least one deflection wire lumen having a distal opening proximal the distal portion, and at least one deflection wire residing in the at least one deflection wire lumen and having a distal end attached to the distal portion.

The balloon dilatation catheter is advanced over the guide wire through the aorta. The deflection wire is pushed towards the distal portion so that the deflection wire bows outward. The balloon dilatation catheter is advanced through the aortic valve, and the dilatation balloon is inflated.

Another embodiment of the present invention comprises a method of treating a patient with a calcified aortic valve. The method comprises introducing a guide wire into a blood vessel. The guide wire is advanced through the aorta to the aortic valve. The guide wire is advanced through the aortic valve. A balloon dilatation catheter is introduced into the blood vessel over the guide wire.

The balloon dilation catheter comprises an elongate body, a distal portion, a guide wire lumen, a dilatation balloon, and a first inflation lumen for inflating the dilation balloon. The balloon dilation catheter further comprises at least one displacement balloon located on the distal portion, and a second inflation lumen for inflating the at least one displacement balloon.

The balloon dilatation catheter is advanced over the guide wire through the aorta. The at least one displacement balloon is inflated. The balloon dilatation catheter is advanced through the aortic valve. The dilatation balloon is inflated.

Further features and advantages of the present invention will become apparent from the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a cross-sectional schematic view of a heart and its major blood vessels with a guide wire disposed within the aorta and heart.

FIG. 1B is an exploded view of the aortic valve showing the position of the guide wire with respect to the aortic valve leaflets.

FIG. 2A is a cross-sectional schematic view of a heart and its major blood vessels with a modified guide wire disposed within the aorta and heart.

FIG. 2B is an exploded view of the aortic valve showing the position of the modified guide wire with respect to the aortic valve leaflets.

FIG. 3A is side view of a catheter with a deflection wire.

FIG. 3B is a cross-sectional view of a heart and its major blood vessels with a catheter disposed within the aorta and heart, the catheter centered within the aorta with a deflection wire.

FIG. 3C is a cross-sectional view of a deflection wire with a circular cross-section.

FIG. 3D is a cross-sectional view of a deflection wire with an oblong cross-section.

FIG. 3E is a cross-sectional view of a deflection wire with a rectangular cross-section.

FIG. 4A is a side view of a catheter with a plurality of deflection balloons.

FIG. 4B is a cross-sectional view of a heart and its major blood vessels with a catheter disposed within the aorta and heart, the catheter centered within the aorta with a plurality of deflection balloons.

FIG. 5 is a cross-sectional view a heart and its major blood vessels with a guide wire disposed within the aorta and heart, the guide wire having a sinusoidal shape.

FIG. 6A is a front perspective view of an embodiment of a valve implant.

FIG. 6B is a cross-sectional side view of the implant of FIG. 6A.

FIG. 6C is an enlarged cross-sectional view of a lower portion of FIG. 6B.

FIG. 6D is a front perspective view of an inflatable support structure of the implant of FIG. 6A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1A is a schematic cross-sectional illustration of the anatomical structure and major blood vessels of a heart 10. Deoxygenated blood is delivered to the right atrium 12 of the heart 10 by the superior and inferior vena cava 14, 16. Blood in the right atrium 12 is allowed into the right ventricle 18 through the tricuspid valve 20. Once in the right ventricle 18, the heart 10 delivers this blood through the pulmonary valve to the pulmonary arteries and to the lungs for a gaseous exchange of oxygen. The circulatory pressures carry this blood back to the heart 10 via the pulmonary veins 26 and into the left atrium 28. Filling of the left ventricle 32 occurs as the mitral valve 30 opens allowing blood to be drawn into the left ventricle 32 for expulsion through the aortic valve 34 and on to the body extremities through the aorta 36. When the heart 10 fails to continuously produce normal flow and pressures, a disease commonly referred to as heart failure occurs.

One cause of heart failure is failure or malfunction of one or more of the valves of the heart 10. For example, the aortic valve 34 can malfunction for several reasons. For example, the aortic valve 34 may be abnormal from birth (e.g., bicuspid, calcification, congenital aortic valve disease), or it could become diseased with age (e.g., acquired aortic valve disease). In such situations, it can be desirable to replace the abnormal or diseased aortic valve 34.

For example, treatment of a calcified aortic valve 34 can be accomplished using minimally invasive procedures, such as balloon catheter dilatation. The balloon catheter described herein, in certain embodiments, generally has at least an elongate body, a guide wire lumen, an inflation lumen, and a dilatation balloon located on a distal portion of the balloon catheter. As illustrated in FIG. 1A, in one embodiment a guide wire 38 is inserted into the femoral artery and traverses the

aorta **36** in a retrograde direction to the aortic valve **34**. Because the guide wire **38** is flexible but is generally straight in the longitudinal direction, the guide wire **38** has a tendency to push against the vessel wall as the guide wire **38** is advanced through the aorta **36**. As illustrated in FIG. 1B, this can result in the guide wire **38** passing through a commissural point of the aortic valve **34** near the vessel wall rather than the central lumen of the aortic valve **34**.

After the guide wire **38** is in place through the aortic valve, a balloon catheter is advanced over the guide wire **38** to the aortic valve **34**. If the guide wire **38** is positioned in a commissural point rather than the central lumen, then the balloon catheter will be required to also pass through the commissural point in order to traverse the aortic valve **34**. However, because the balloon catheter has a larger diameter than the guide wire **38**, the balloon catheter may abut against portions of the calcified aortic valve **34** leaflets, which will tend to impede passage of the balloon catheter through the aortic valve **34**. This is especially problematic when the commissures of the calcified aortic valve **34** are fused, thereby further resisting passage of the balloon catheter through the aortic valve **34**.

Therefore, in order to facilitate passage of the balloon catheter or any other catheter through the aortic valve **34**, the catheter and guide wire **38** preferably should pass through the central lumen of the aortic valve **34** as illustrated in FIGS. 2A and 2B. As will be explained in detail below, this can be accomplished by pushing or displacing the catheter away from the vessel wall near the aortic valve **34** using certain techniques, methods and apparatus disclosed herein.

One method of displacing the catheter away from the vessel wall is to use a deflection member that is incorporated with the catheter. The deflection member can be configured to have a first position in which at least a portion of the deflection member is positioned near a longitudinal axis of the catheter and a second position in which a portion of the deflection member is moved away from the longitudinal axis of the catheter. In some embodiments, the deflection member can be, for example, a wire, a balloon, or a lever. FIG. 3A illustrates an embodiment of a catheter **40** having a deflection wire **42**. The distal end or a distal portion of the deflection wire **42** is attached to a distal portion **46** of the catheter **40**. The catheter **40** also has a deflection wire lumen **44** in which a portion of the deflection wire **42** resides. The deflection wire lumen **44** can have a proximal opening **48** and a distal opening **50** that is proximal the distal portion **46** where the deflection wire **42** is attached. A portion of the deflection wire **42** distal the distal opening **50** is uncovered and exposed.

The catheter **40** can be displaced from the vessel wall by pushing the deflection wire **42** towards the distal end of the catheter **40**. As the deflection wire **42** is advanced towards the distal end of the catheter **40**, the exposed portion of the deflection wire **42** distal the distal opening **50** will bow outwards and displace the catheter **40** and guide wire **38** away from the vessel wall and to the central lumen as illustrated in FIGS. 3A and 3B. If the deflection wire **42** is facing the center of the vessel rather than the vessel wall, the catheter **40** can be rotated so that the deflection wire **42** is facing the vessel wall and be capable of displacing the catheter when the deflection wire **42** is distally advanced.

In other embodiments, the catheter **40** has a plurality of deflection wires **42** spaced approximately evenly around the periphery of the catheter **40**. Each deflection wire **42** can be individually advanced or be advanced together as a group. A plurality of deflection wires **42** can help increase the likelihood of properly centering the catheter **40** and guide wire **38** while providing additional stability.

As illustrated in FIGS. 3C, 3D and 3E, the deflection wire **42** can have, for example, a round cross-sectional area, an oblong or elliptical cross-sectional area, or a rectangular cross-sectional area. A ribbon-like deflection wire **42** with a rectangular, elliptical or oblong cross-sectional area will preferentially bend in one direction. The deflection wire **42** can be oriented so that the wider portion of the deflection wire **42** faces the vessel wall such that when the deflection wire **42** contacts the vessel wall, a relatively large surface area of the deflection wire **42** makes contact with the vessel wall. This allows the deflection wire **42** to spread out the force exerted on the vessel wall over a larger area.

The deflection wire **42** can be made from a variety of materials such as stainless steel, Nitinol, MP35N or other metallic materials commonly used in medical devices. Alternatively, the deflection wire **42** can be made from a polymer such as polyimide, PEEK, polypropylene or other polymer based materials commonly used in medical devices.

In another embodiment, the method and apparatus for displacing the catheter away from the vessel wall comprises a displacement balloon that is used with the catheter. For example, FIGS. 4A and 4B illustrate an embodiment of a catheter **40** having at least one displacement balloon **52** that can be inflated to displace the catheter **40** and guide wire **38** away from the vessel wall. The embodiment illustrated in FIGS. 4A and 4B comprises two displacement balloons **52** located on or near the distal portion of the catheter **40**. The displacement balloons **52** can be inflated and deflated using a first inflation lumen **54** that extends from the proximal portion of the catheter **40** to the displacement balloons **52**. When the displacement balloons **52** are inflated, the catheter **40** is displaced away from the blood vessel wall such that the catheter **40** and guide wire **38** are located in or can pass through the central lumen of the aortic valve **34**. In other embodiments, the catheter **40** can have more or less than 2 displacement balloons. In other embodiments, the displacement balloon can be an annular balloon.

In another embodiment, the method and apparatus for displacing the catheter away from the vessel wall comprises using a guide wire that includes one or more bends that allow the guide wire and catheter to pass through the central lumen of the aortic valve. FIG. 5 illustrates an embodiment of a guide wire **38** that is sinusoidal in shape. The sinusoidal guide wire **38** has a series of peaks **56**, an amplitude between about 2 mm to 60 mm in height or between about 2 mm to 30 mm in height when measured from peak to peak, and a period between about 2 to 60 mm in length. The amplitude of the sinusoidal guide wire **38** is preferably about half the diameter of the aorta **36** or aortic valve **34** so that a peak **56** of the guide wire **38** can be located in the central lumen of the aortic valve **34** by rotating and advancing or retracting the guide wire **38** after the guide wire **38** has been inserted through the aortic valve **34**.

Although the methods and devices described above have been described in connection with guiding a catheter through an aortic valve, the methods and devices described above can also be used to guide a catheter through any heart valve or blood vessel valve. In addition, the methods and devices described above can be used to guide a valve implant deployment catheter so that the valve implant can be properly positioned in the patient's heart or vasculature. Embodiments of valve implants, deployment catheters and the methods of their use are more fully described in U.S. Publication No. 2005/0273160 A1 filed Apr. 22, 2005, U.S. Publication No. 2006/0025855 A1 filed May 5, 2005, and U.S. Publication No. 2007/0005133 A1 filed Jun. 7, 2006, each of which is hereby incorporated by reference in its entirety.

An example of an embodiment of a valve implant is illustrated in FIGS. 6A-6D. The implant **100** of the illustrated embodiment generally comprises an inflatable cuff or body **102**, which is configured to support a valve that is coupled to the cuff **102**. As will be explained in more detail below, the valve is configured to move in response to the hemodynamic movement of the blood pumped by the heart **10** between an “open” configuration where blood can flow through the implant **100** in a first direction (labeled A in FIG. 6B) and a “closed” configuration whereby blood is prevented from back flowing through the valve in a second direction B (labeled B in FIG. 6B).

In the illustrated embodiment, the cuff **102** comprises a thin flexible tubular material **106** such as a flexible fabric or thin membrane with little dimensional integrity. As will be explained in more detail below, the cuff **102** can be changed preferably, in situ, to a support structure to which other components (e.g., the valve) of the implant **100** can be secured and where tissue ingrowth can occur. Uninflated, the cuff **102** is preferably incapable of providing support. In one embodiment, the cuff **102** comprises Dacron, PTFE, ePTFE, TFE or polyester fabric **106** as seen in conventional devices such as surgical stented or stent less valves and annuloplasty rings. The fabric **106** thickness may range from about 0.002 inches to about 0.020 inches of an inch depending upon material selection and weave. Weave density may also be adjusted from a very tight weave to prevent blood from penetrating through the fabric **106** to a looser weave to allow tissue to grow and surround the fabric **106** completely. Additional compositions and configurations of the cuff **102** will be described in more detail below.

With continued reference to FIGS. 6B-6D, in the illustrated embodiment, the implant **100** includes an inflatable structure **107** that forms one or more of inflation channels **120**, which in illustrated embodiment are formed in part by a pair of distinct balloon rings or toroids **108a**, **108b**. The rings **108a**, **108b** in this embodiment are positioned at the proximal and distal ends **126**, **128** of the cuff **102**. As will be explained below, the rings **108** can be secured to the body **102** in any of a variety of manners. With reference to FIG. 6C, in the illustrated embodiment, the rings **108** are secured within folds **110** formed at the proximal and distal ends **126**, **128** of the cuff **102**. The folds **110**, in turn, are secured by sutures or stitches **112**. See FIG. 6C.

The illustrated inflatable structure **107** also includes inflatable struts **114**, which in the illustrated embodiment are formed from an annular zig-zag pattern having three proximal bends **116** and three distal bends **118**. As best seen in FIG. 6C, the struts **114** can be secured to the cuff **102** within pockets **115** of cuff material by sutures **112**. Of course, as will be explained in more detail, other embodiments other configurations can be used to secure the struts **114** to the fabric **106**.

As mentioned above, the inflatable rings **108** and struts **114** form the inflatable structure **107**, which, in turn, defines the inflation channels **120**. The inflation channels **120** receive inflation media **122** to generally inflate the inflatable structure **107**. When inflated, the inflatable rings and struts **108**, **114** provide structural support to the inflatable implant **100** and/or help to secure the implant **100** within the heart. Uninflated, the implant **100** is a generally thin, flexible shapeless assembly that is preferably incapable of support and is advantageously able to take a small, reduced profile form in which it can be percutaneously inserted into the body. As will be explained in more detail below, in modified embodiments, the inflatable structure **107** may comprise any of a variety of configurations of inflation channels **120** that

can be formed from other inflatable members in addition to or in the alternative to the inflatable rings **108** and struts **114** shown in FIGS. 6A and 6B. In addition, the inflatable media **122** and methods for inflating the inflatable structure **107** will be described in more detail below.

With particular reference to FIG. 6D, in the illustrated embodiment, the proximal ring **108a** and struts **114** are joined such that the inflation channel **120** of the proximal ring **108a** is in fluid communication with the inflation channel **120** of the struts **114**. In contrast, the inflation channel **120** of the distal ring **108b** is not in communication with the inflation channels **120** of the proximal ring **108a** and struts **114**. In this manner, the inflation channels of the (i) proximal ring **108a** and struts **115** can be inflated independently from the (ii) distal ring **108b**. As will be explained in more detail below, the two groups of inflation channels **120** are preferably connected to independent fluid delivery devices to facilitate the independent inflation. It should be appreciated that in modified embodiments the inflatable structure can include less (i.e., one common inflation channel) or more independent inflation channels. For example, in one embodiment, the inflation channels of the proximal ring **108a**, struts **114** and distal ring **108b** can all be in fluid communication with each other such that they can be inflated from a single inflation device. In another embodiment, the inflation channels of the proximal ring **108a**, struts **114** and distal ring **108b** can all be separated and therefore utilize three inflation devices.

With reference to FIG. 6B, in the illustrated embodiment, the proximal ring **108a** has a cross-sectional diameter of about 0.090 inches. The struts have a cross-sectional diameter of about 0.060 inches. The distal ring **108b** has a cross-sectional diameter of about 0.090 inches diameter.

In prior art surgically implanted valves, the valve generally includes a rigid inner support structure that is formed from polycarbonate, silicone or titanium wrapped in silicone and Dacron. These surgical valves vary in diameter for different patients due to the respective implantation site and orifice size. Generally the largest diameter implantable is the best choice for the patient. These diameters range from about 16 mm to 30 mm.

As mentioned above, the implant **100** allows the physician to deliver a valve via catheterization in a lower profile and a safer manner than currently available. When the implant **100** is delivered to the site via a delivery catheter **300**, the implant **100** is a thin, generally shapeless assembly in need of structure and definition. At the implantation site, the inflation media **122** (e.g., a fluid or gas) may be added via a catheter lumen to the inflation channels **120** providing structure and definition to the implant **100**. The inflation media **122** therefore comprises part of the support structure for implant **100** after it is inflated. The inflation media **122** that is inserted into the inflation channels **120** can be pressurized and/or can solidify in situ to provide structure to the implant **100**. Additional details and embodiments of the implant **100**, can be found in U.S. Pat. No. 5,554,185 to Block, the disclosure of which is expressly incorporated in its entirety herein by reference.

The body **102** of the valve implant **100** may be made from many different materials such as Dacron, TFE, PTFE, ePTFE, woven metal fabrics, braided structures, or other generally accepted implantable materials. These materials may also be cast, extruded, or seamed together using heat, direct or indirect, sintering techniques, laser energy sources, ultrasound techniques, molding or thermoforming technologies. Since the body **102** generally surrounds the inflation lumens **120**, which can be formed by separate members (e.g., rings **108**),

the attachment or encapsulation of these lumens **120** can be in intimate contact with the body material **106** or a loosely restrained by the surrounding material **106**. These inflation lumens **120** can also be formed also by sealing the body material **106** to create an integral lumen from the body **102** itself. For example, by adding a material such as a silicone layer to a porous material such as Dacron, the fabric **106** can resist fluid penetration or hold pressures if sealed. Materials may also be added to the sheet or cylinder material to create a fluid tight barrier. However, in the illustrated embodiment of FIGS. **6A** and **6B**, the inflation lumens **120** are formed by balloons, which form the separate inflation components **108a**, **108b**, **122**, which are, in turn, secured to the material **106**.

Various shapes of the body **102** may be manufactured to best fit anatomical variations from person to person. As described above, these may include a simple cylinder, a hyperboloid, a device with a larger diameter in its mid portion and a smaller diameter at one or both ends, a funnel type configuration or other conforming shape to native anatomies. The shape of the implant **100** is preferably contoured to engage a feature of the native anatomy in such a way as to prevent the migration of the device in a proximal or distal direction. In one embodiment the feature that the device engages is the aortic root or aortic bulb, or the sinuses of the coronary arteries. In another embodiment the feature that the device engages is the native valve annulus, the native valve or a portion of the native valve. In certain embodiments, the feature that the implant **100** engages to prevent migration has a diametral difference between 1% and 10%. In another embodiment the feature that the implant **100** engages to prevent migration the diameter difference is between 5% and 40%. In certain embodiments the diameter difference is defined by the free shape of the implant **100**. In another embodiment the diameter difference prevents migration in only one direction. In another embodiment, the diameter difference prevents migration in two directions, for example proximal and distal or retrograde and antigrade. Similar to surgical valves, the implant **100** will vary in diameter ranging from about 14 mm to about 30 mm and have a height ranging from about 10 mm to about 30 mm in the portion of the implant **100** where the leaflets of the valve are mounted. Portions of the implant **100** intended for placement in the aortic root may have larger diameters preferably ranging from about 20 to about 45 mm.

Different diameters of valves will be required to replace native valves of various sizes. For different locations in the anatomy, different lengths of valves or anchoring devices will also be required. For example a valve designed to replace the native aortic valve needs to have a relatively short length because of the location of the coronary artery ostium (left and right arteries). A valve designed to replace or supplement a pulmonary valve could have significantly greater length because the anatomy of the pulmonary artery allows for additional length.

The various methods and techniques described above provide a number of ways to carry out the invention. Of course, it is to be understood that not necessarily all objectives or advantages described may be achieved in accordance with any particular embodiment described herein. Thus, for example, those skilled in the art will recognize that the methods may be performed in a manner that achieves or optimizes

one advantage or group of advantages as taught herein without necessarily achieving other objectives or advantages as may be taught or suggested herein.

Furthermore, the skilled artisan will recognize the interchangeability of various features from different embodiments disclosed herein. Similarly, the various features and steps discussed above, as well as other known equivalents for each such feature or step, can be mixed and matched by one of ordinary skill in this art to perform methods in accordance with principles described herein. Additionally, the methods which is described and illustrated herein is not limited to the exact sequence of acts described, nor is it necessarily limited to the practice of all of the acts set forth. Other sequences of events or acts, or less than all of the events, or simultaneous occurrence of the events, may be utilized in practicing the embodiments of the invention.

Although the invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. Accordingly, the invention is not intended to be limited by the specific disclosures of preferred embodiments herein

What is claimed is:

1. A method of treating a patient with a calcified aortic valve, the method comprising:

introducing a guide wire into a blood vessel;

advancing the guide wire through the aorta to the aortic valve;

advancing the guide wire through the aortic valve;

introducing a balloon dilatation catheter into the blood vessel over the guide wire, the balloon dilatation catheter comprising an elongate body, a distal portion, a guide wire lumen, an inflation lumen, a dilatation balloon, at least one deflection wire lumen, the at least one deflection wire lumen having a distal opening proximal the distal portion, at least one deflection wire residing in the at least one deflection wire lumen and having a distal end attached to the distal portion;

advancing the balloon dilatation catheter over the guide wire through the aorta;

pushing the deflection wire towards the distal portion so that the deflection wire bows outward without inflating the dilatation balloon;

advancing the balloon dilatation catheter with a bowed outward deflection wire through the aortic valve; and inflating the dilatation balloon.

2. The method of treating a patient of claim **1**, wherein the at least one deflection wire has an oblong cross-sectional area.

3. The method of treating a patient of claim **2**, wherein the at least one deflection wire has a generally rectangular cross-sectional area.

4. The method of treating a patient of claim **2**, wherein the at least one deflection wire has a generally elliptical cross-sectional area.

5. The method of treating a patient of claim **1**, wherein the at least one deflection wire comprises a plurality of deflection wires spaced approximately evenly around the periphery of the catheter.

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